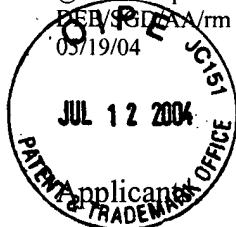


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mitchell P. Fink and Howland Shaw Warren, Jr.

Application No.: 10/679,040

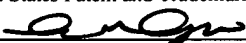
Group Art Unit: 1614

Filed: October 3, 2003

Examiner: Not Yet Assigned

Confirmation No.: 1662

Title: METHOD FOR PREVENTING ACUTE RENAL FAILURE

<b>CERTIFICATE OF MAILING OR TRANSMISSION</b>	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references (AL-AN & AR-AT2) are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Alexander Akhiezer

Alexander Akhiezer

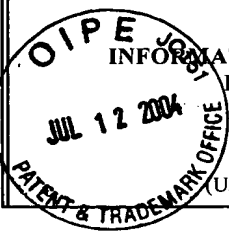
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Concord, MA 01742-9133

Dated: 7/9/04

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3258.1000-004	APPLICATION NO. 10/679,040	
 <p>May 17, 2004 (Use several sheets if necessary)</p>		FIRST NAMED INVENTOR Mitchell P. Fink		FILING DATE October 3, 2003
		EXAMINER Not Yet Assigned	CONFIRMATION NO. 1662	GROUP 1614

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	5,354,771	10-NOV-1994	Walser
	AB	5,210,098	05-NOV-1993	Nath
	AC	5,798,388	25-AUG-98	Katz
	AD	5,952,384	14-SEP-99	Katz
	AE	6,051,609	18-APR-00	Yu <i>et al.</i>
	AF	5,665,776	09-SEP-97	Yu <i>et al.</i>
	AG	5,621,006	15-APR-97	Yu <i>et al.</i>
	AH	5,561,157	01-OCT-96	Yu <i>et al.</i>
	AI	5,091,171	25-FEB-92	Yu <i>et al.</i>
	AJ	5,968,727	19-OCT-99	Brunengraber <i>et al.</i>
	AK	5,876,916	02-MAR-99	Brunengraber <i>et al.</i>
	AA2	5,667,962	16-SEP-97	Brunengraber <i>et al.</i>
	AB2	6,086,789	11-JUL-00	Brunengraber <i>et al.</i>
	AC2	5,939,459	17-AUG-99	Katz
	AD2	5,648,380	15-JUL-97	Martin
	AE2	5,652,274	29-JUL-97	Martin
	AF2	5,658,957	19-AUG-97	Martin
	AG2	5,658,956	19-AUG-97	Martin <i>et al.</i>
	AH2	5,981,606	09-NOV-99	Martin
	AI2	5,100,677	31-MAR-92	Veech
	AJ2	5,674,912	07-OCT-97	Martin
	AK2	5,874,479	23-FEB-99	Martin
	AA3	5,238,684	08-24-1993	Fregly <i>et al.</i>
	AB3	5,756,469	05-26-1998	Beale
	AC3	4,663,166	05-05-1987	Veech
	AD3	5,744,498	28-APR-98	Stanko

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>May 17, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3258.1000-004		APPLICATION NO. 10/679,040	
	FIRST NAMED INVENTOR Mitchell P. Fink		FILING DATE October 3, 2003	
	EXAMINER Not Yet Assigned	CONFIRMATION NO. 1662	GROUP 1614	

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EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE3	5,702,880	30-DEC-97	Segall <i>et al.</i>
	AF3	5,612,374	18-MAR-97	Stanko
	AG3	4,981,687	01-JAN-91	Fregly <i>et al.</i>
	AH3	6,143,784	07-NOV-00	Greenhaff <i>et al.</i>
	AI3	5,580,902	03-DEC-96	Yu <i>et al.</i>
	AJ3	3,988,470	26-OCT-76	Van Scott <i>et al.</i>
	AK3	3,920,835	18-NOV-75	Van Scott <i>et al.</i>
	AA4	3,984,556	05-OCT-76	Hardtmann
	AB4	4,548,937	22-OCT-85	Stanko
	AC4	5,134,162	28-JUL-92	Stanko
	AD4	4,645,764	24-FEB-87	Stanko
	AE4	4,812,479	14-MAR-89	Stanko
	AF4	4,874,790	17-OCT-89	Stanko
	AG4	4,415,576	15-NOV-83	Stanko
	AH4	4,351,835	28-SEP-82	Stanko
	AI4	5,294,641	15 Mar 94	Stanko
	AJ4	4,988,515	29 Jan 91	Buckberg
	AK4	5,075,210	24 Dec 91	Wikman-Coffelt
	AA5	5,633,285	27 May 97	Martin
	AB5	5,066,578	19 Nov 91	Wikman-Coffelt
	AC5	5,714,515	3 Feb 98	Bunger
	AD5	5,536,751	16 Jul 96	Bunger
	AE5	5,801,198	1 Sep 98	Stanko, <i>et al.</i>
	AF5	5,480,909	2 Jan 96	Stanko
	AG5	5,147,650	15 Sep 92	Fregly, <i>et al.</i>
	AH5	5,256,697	26 Oct 93	Miller, <i>et al.</i>

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>May 17, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3258.1000-004	APPLICATION NO. 10/679,040	
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U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AI5	5,312,985	17 May 94	Dhaon, <i>et al.</i>
	AJ5	5,395,822	7 Mar 95	Izumi, <i>et al.</i>
	AK5	5,472,980	5 Dec 95	Miller
	AA6	5,508,308	16 Apr 96	Miller, <i>et al.</i>
	AB6	5,843,024	1 Dec 98	Brasile
	AC6	5,863,938	26 Jan 99	Martin
	AD6	4,970,143	13 Nov 90	Guidoux, <i>et al.</i>

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
	AL	EP 0 345 082 A2	12-06-1989	Kabushiki Kaisha Hayashibara Seibutsu Kagaku Kenkyujo, <i>et al.</i>	
	AM	WO 01/24793 A1	04-12-2001	Masstrace, Inc. <i>et al.</i>	
	AN	WO 00/69431	11-23-2000	Cellular Sciences, Inc. <i>et al.</i>	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Banda, M.A. and Granger, D.N., "Mechanism and Protection from Ischemic Intestinal Injury," <i>Transplantation Proceedings</i> , 28:2595-2597 (1996).	
AS	Cicalese, L., <i>et al.</i> , "Pyruvate Prevents Ischemia-Reperfusion Mucosal Injury of Rat Small Intestine," <i>Amer. J. of Surg.</i> , 171:97-100; discussion 100-101 (1996).	
AT	Crestanello, J.A., <i>et al.</i> , "Pyruvate Improves Myocardial Tolerance to Reperfusion Injury by Acting as an Antioxidant: A Chemiluminescence Study," <i>Surgery</i> , 124:92-99 (1998).	

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	EXAMINER Not Yet Assigned		CONFIRMATION NO. 1662	GROUP 1614

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	AU	DeBoer, L.W., <i>et al.</i> , "Pyruvate Enhances Recovery of Rat Hearts After Ischemia and Reperfusion by Preventing Free Radical Generation," <i>American Journal of Physiology</i> , 265:H1571-H1576 (1993).
	AV	Kurose, I., <i>et al.</i> , "Ischemia/Reperfusion-Induced Microvascular Dysfunction: Role of Oxidants and Lipid Mediators," <i>Amer. J. Physiol.</i> , 272:H2976-H2982 (1997).
	AW	Margolis, S.A. and Coxon, B., "Identification and Quantitation of the Impurities in Sodium Pyruvate," <i>Analytical Chemistry</i> , 58:2504-2510 (1986).
	AX	O'Donnell-Tormey, J., <i>et al.</i> , "Secretion of Pyruvate. An Antioxidant Defense of Mammalian Cells," <i>J. of Experimental Medicine</i> , 165:500-514 (1987).
	AY	Perera, A., <i>et al.</i> , "High Resolution <sup>1</sup> H NMR Investigations of the Reactivities of Alpha-Keto Acid Anions with Hydrogen Peroxide," <i>Free Radical Research</i> , 26:145-157 (1997).
	AZ	Salahudeen, A.K., <i>et al.</i> , "Hydrogen Peroxide-induced Renal Injury: A Protective Role for Pyruvate In Vitro and In Vivo," <i>Journal of Clinical Investigation</i> , 88:1886-1893 (1991).
	AR2	Sawyer, D.T., <i>et al.</i> , "Reactivity of Superoxide Ion with Ethyl Pyruvate, $\alpha$ -Diketones, and Benzil in Dimethylformamide," <i>Journal of Organic Chemistry</i> , 48:3733-3736 (1983).
	AS2	Varma, S.D., <i>et al.</i> , "Prevention of Intracellular Oxidative Stress to Lens by Pyruvate and Its Ester," <i>Free Radical Research</i> , 28:131-135 (1998).
	AT2	Sims, C.A., <i>et al.</i> , "Intravenous Pyruvate and Pyruvate Ethyl Ester Ameliorate Intestinal Mucosal Injury Following Ischemia/Reperfusion," <i>Surgical Forum</i> , Volume L: 246-248 (1999).

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